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| APPLICATION NO.            | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|----------------------------|-------------|-----------------------|----------------------|------------------|
| 10/645,055                 | 08/21/2003  | Douglas A. Devens JR. | 10527-443001         | 6549             |
| 26161                      | 7590        | 06/10/2008            | EXAMINER             |                  |
| FISH & RICHARDSON PC       |             |                       | CAMPBELL, VICTORIA P |                  |
| P.O. BOX 1022              |             |                       |                      |                  |
| MINNEAPOLIS, MN 55440-1022 |             |                       | ART UNIT             | PAPER NUMBER     |
|                            |             |                       | 3763                 |                  |
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|                            |             |                       | 06/10/2008           | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/645,055             | DEVENS ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | VICTORIA P. CAMPBELL   | 3763                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 March 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-45 is/are pending in the application.  
 4a) Of the above claim(s) 9,11,13,15,16,18-26 and 29-42 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-8,10,12,14,17,27,28 and 43-45 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 26 November 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 11/28/03, 1/31/05.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Election/Restrictions***

1. Applicant's election without traverse of Species A as defined by the examiner in the reply filed on March 13, 2008 is acknowledged. Applicant has indicated that claims 1-8, 10, 12, 14, 17, 27, 28, 32-37, and 39-45 all read on the elected species. The examiner hereby further withdraws claims 32-37 from examination for being dependent on claim 31, which was not indicated as part of the elected species.
2. After further investigation into the application, the examiner has required additional restriction between inventions as follows:

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-38 and 43-45, drawn to a medical balloon.
  - II. Claims 39-42, drawn to a method of making a medical balloon.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the device could be made by a process of dipping.
5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above

and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement

will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Tim French on May 30, 2008 a provisional election was made without traverse to prosecute the invention of Invention I, claims 1-38 and 43-45. Affirmation of this election must be made by applicant in replying to this Office action. Claims 39-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This is the initial Office Action based on the 10/645055 application filed August 21, 2003. Claims 1-8, 10, 12, 14, 17, 27, 28, and 43-45 as elected are currently pending and considered below.

### ***Drawings***

9. The drawings were received on November 26, 2003. These drawings are accepted by the examiner.
10. The drawings are objected to because in Figure 2, the reference character  $T_{IC}$  is used to denote the thickness of the outer layer in the cone portion, but in the specification it refers to the inner layer in the cone portion. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

11. The use of several trademarks has been noted in this application. These should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

12. The disclosure is objected to because of the following informalities:

Related applications should be updated to include serial numbers and statuses.  
Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 6, 7, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 7 recite the limitation "a first portion of the body portion" which does not have antecedent basis within the specification. The body of the elected species has only one portion, and the examiner is unsure as to whether applicant means "a first

portion of the balloon" or "the body portion". Examiner understands the phrase to mean "a first portion of the balloon" and defines the first portion of the balloon to mean the waist portion.

Claim 17 recites the limitation "the balloon has a body portion and a cone portion that are more flexible than the body portion". The body portion can not be more flexible than itself. The examiner, in light of the specification, understands this to mean "the balloon has a waist portion and a cone portion that are more flexible than the body portion".

### ***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-8, 10, 12, 14, 17, 27, 28, and 43-45 as best understood by the examiner are rejected under 35 U.S.C. 102(b) as being anticipated by USPGPub 2001/0019762 A1 to Nazarova et al.

Regarding claims 1-8, 10, 12, 14, and 17, Nazarova et al disclose a balloon (14) comprising a first portion (16, labeled as 18 in Fig. 2) and a second portion (13) which vary in thickness (Fig. 1; Paragraph [0019]), wherein the first and second portions have different compositions (Paragraphs [0015], [0016], and [0026]), the first portion has a waist portion thicker than other portions of the balloon, including the cones (Paragraph

[0009]) and extends substantially the entire length of the balloon (Fig. 1), and the second portion is disposed entirely on the first portion (Fig. 2). Nazarova et al also disclose that the thickness of the first and second portions is generally constant in the cone portion and that the first and second portions extend substantially the entire length of the balloon. Further, Nazarova et al disclose many different materials for the first and second portions, which could be combined in such a way to make the waist and cone portions more flexible than the body portion.

Regarding claims 27 and 28, Nazarova et al disclose a balloon comprising a body portion (24), a cone portion (26), and a first layer of polymer (13) extending across a portion of the body portion and the cone portion having different thickness in the body portion than the cone portion (Paragraph [0009]), wherein the thickness of the first layer in the cone portion is substantially constant (Fig. 1).

Regarding claims 43-45, Nazarova et al disclose a medical balloon (14) comprising a plurality of at least two layers (Fig. 2) formed of a first material (16/18) and a second material (13) different from the first material (Paragraphs [0015], [0016], and [0026]) wherein at least one layer varies in thickness (Fig. 1), and wherein the balloon comprises a body portion (24) and a tapered portion (26) having different stiffness (which can be imparted by varying the thickness as well as the materials as described in the specification).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell  
Examiner, AU 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763